



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/716,862	11/20/2003	George R. Dodge	06510029US	5643

7590 01/09/2006

McGuire Woods LLP
Suite 1800
1750 Tysons Blvd.
McLean, VA 22102

EXAMINER

REIDEL, JESSICA L

ART UNIT	PAPER NUMBER
----------	--------------

3766

DATE MAILED: 01/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

E

Office Action Summary

Application No.

10/716,862

Applicant(s)

DODGE ET AL.

Examiner

Jessica L. Reidel

Art Unit

3766

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 10-17 is/are allowed.
- 6) ☒ Claim(s) 1-9, 18, 20-24, 26-31 and 36 is/are rejected.
- 7) ☒ Claim(s) 19, 25 and 32-35 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 November 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Acknowledgement is made of Applicant's Amendment, which was received by this Office on November 9, 2005. No Claims have been cancelled. Claims 1-26 are active. Claims 27-36 are new and active.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-7, 9, 18, 20-24, 26 and 30-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Michelson (U.S. 6,120,502). As to Claim 1, Michelson discloses a bone growth inhibiting device 10 comprising a power source 60 (see Michelson Abstract, column 7, lines 40-47, column 9, lines 9-10 and lines 30-38 and column 10, lines 22-31) for generating "positive current" where bone growth is "not desired" (see Michelson column 10, lines 50-52). Device 10 of Michelson also comprises at least one anode 96 of electrode 30, read as one electrode, in electrical communication with the power source 60 (see Michelson column 9, lines 17-18 and column 10, lines 23-31) adapted to apply the positive current to a predetermined location of the bone (see Michelson Fig. 3A and column 10, lines 50-52). The Examiner takes the position that "to inhibit" biologically is synonymous with all verbs that encompass "to decrease, limit, or block the action or function of" including "to reduce" and makes reference to the dictionary definition of "to inhibit", to Applicant's Title of invention and to Applicant's disclosure pages 6 and 9-11.

Art Unit: 3766

4. As to Claim 2, Michelson discloses that one anode 96 of electrode 30, read as one electrode, is in electrical communication with the power source 60 and a cathode of electrode 30, read as another electrode is also in electrical communication with the power source 60 (see Michelson column 4, lines 23-35 and column 10, lines 15-31).

5. As to Claim 3, Michelson further discloses an alternate embodiment of device 10 comprising at least one electrode 230 comprising an electrically conductive threaded portion 200 (see Michelson column 12, lines 25-34).

6. As to Claim 4, Michelson discloses that device 10 further comprises a controller 70 in electrical communication with the power source 60 (see Michelson column 9, lines 45-46) and the at least one electrode 30 (see Michelson column 9, lines 15-24). The controller 70 distributes a predetermined current to the at least one electrode 30 (see Michelson column 9, lines 25-27).

7. As to Claim 5, Michelson discloses that controller 70 of device 10 regulates the frequency and duration the current is distributed to the at least one electrode 30 (see Michelson column 9, lines 30-35).

8. As to Claim 6, Michelson discloses that controller 70 of device 10 regulates an amount of the current applied to the at least one electrode 30 (see Michelson column 9, lines 30-35).

9. As to Claim 7, Michelson discloses that controller 70 of device 10 regulates an amount of the current applied to the at least one electrode 30 and the frequency and duration the current is distributed to the at least one electrode 30 via a waveform generator, a voltage generator or a clock means (see Michelson column 9, lines 30-35). It is inherent that these types of control circuitry for controller 70 were programmed to carry out the scope of the invention.

Art Unit: 3766

10. As to Claim 9, Michelson discloses that one anode 96 of electrode 30, read as one electrode, is in electrical communication with the power source 60 and a cathode of electrode 30, read as another electrode is also in electrical communication with the power source 60 (see Michelson column 4, lines 23-35 and column 10, lines 15-31). Michelson further discloses that the cathode electrode delivers negative electrical current and the anode electrode delivers positive electrical current (see Michelson column 4, lines 23-35). The Examiner takes the position that the current delivered to these two electrodes is thus different.

11. As to Claim 18, Michelson discloses a method comprising the steps of positioning at least one anode 96 of electrode 30 at a portion of a vertebra V near an outside of a curve of a spine (far right side of V in Michelson Fig. 2) and applying a bone growth inhibiting current to that portion of the vertebra without reducing growth of the vertebra near the inside of the curve (where the cathode of electrode 30 sits at the far left side of V in Michelson Fig. 2) (see Michelson Figs. 2 and 4 and column 8, lines 27-37). The Examiner takes the position that the right side of Fig. 2 is the "outside curve of the vertebra" and the left side of Fig. 2 is the "inside curve of the vertebra". The Examiner notes that positive inhibiting current is applied to the outside curve in this embodiment and negative inducing current is applied to the inside of the curve in this embodiment and thus device 10 is inherently capable of correcting the curvature of a spine (see Michelson column 8, lines 27-38, column 10, lines 62-67 and column 11, lines 1-32).

12. As to Claim 20, Michelson discloses a method comprising the steps of positioning at least one anode 96 of electrode 30 at a portion of a vertebra V near an outside of a curve of a spine (far right side of V in Michelson Fig. 2) and applying a bone growth inhibiting current to that

Art Unit: 3766

portion of the vertebra without reducing growth of the vertebra near the inside of the curve (where the cathode of electrode 30 sits at the far left side of V in Michelson Fig. 2) (see Michelson Figs. 2 and 4 and column 8, lines 27-37). The Examiner takes the position that “near” is a relative term and both the anode electrode and the cathode electrode are “near” the outside of the curve of the spine. Michelson also discloses that both electrodes are in electrical communication with the power source 60 to generate a bone reducing positive current (see Michelson column 9, lines 17-18 and column 10, lines 23-31). Michelson also discloses that device 10 further comprises a controller 70 in electrical communication with the power source 60 (see Michelson column 9, lines 45-46) and the anode and cathode (see Michelson column 9, lines 15-24). The controller 70 distributes a predetermined current to anode and cathode (see Michelson column 9, lines 25-27).

13. As to Claims 21 and 23, Michelson discloses that controller 70 of device 10 regulates an amount of the current applied to the at least one electrode 30 and the frequency and duration the current is distributed to the at least one electrode 30 via a waveform generator, a voltage generator or a clock means (see Michelson column 9, lines 30-35). It is inherent that these types of control circuitry for controller 70 were programmed to carry out the scope of the invention.

14. As to Claim 22, Michelson discloses that one anode 96 of electrode 30, read as one electrode, is in electrical communication with the power source 60 and a cathode of electrode 30, read as another electrode is also in electrical communication with the power source 60 (see Michelson column 4, lines 23-35 and column 10, lines 15-31). Michelson further discloses that the cathode electrode delivers negative electrical current and the anode electrode delivers

Art Unit: 3766

positive electrical current (see Michelson column 4, lines 23-35). The Examiner takes the position that the current delivered to these two electrodes is thus different.

15. As to Claims 24 and 31, Michelson discloses that the cathode of the electrode 30 provides a bone stimulating current (see Michelson Abstract). The Examiner takes the position that the right side of Fig. 2 is the “outside curve of the vertebra” and the left side of Fig. 2 is the “inside curve of the vertebra”. The Examiner notes that positive inhibiting current is applied to the outside curve in this embodiment and negative inducing current is applied to the inside of the curve in this embodiment. Michelson also discloses that the negative bone growth stimulating current is applied with a second cathode electrode (see Michelson column 8, lines 27-38, column 10, lines 62-67 and column 11, lines 1-32).

16. As to Claim 26, the Examiner takes the position that “near” is a relative term and both the anode electrode and the cathode electrode of Michelson are placed “near a growth plate”.

17. As to Claim 30, it is inherent that vertebra are located along the entire length of the spine. The Examiner takes the position that vertebra is located substantially at the apex of the curve.

Claim Rejections - 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

19. Claims 8, 27-29 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michelson. As to Claim 8, Michelson discloses the claimed invention as discussed above except that the current effective to inhibit/reduce bone growth is not specified to be at least 50 μ A. It

Art Unit: 3766

would have been obvious to one having ordinary skill in the art at the time the invention was made to make the power source and the at least one electrode deliver a positive current/charge of at least 50 μA , since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art.

20. As to Claims 27-28, Michelson discloses the claimed invention as discussed above except that the currents delivered to each electrode are not specified to be 50 μA and 35 μA respectively. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the power source a positive current/charge of at least 50 μA and 35 μA , since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art.

21. As to Claim 29, Michelson discloses that the bone grown stimulating current is under 20 μA (see Michelson column 9, lines 25-27). Michelson discloses the claimed invention as discussed above except that the current effective to inhibit/reduce bone growth is not specified to be at least 50 μA . It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the power source and the at least one electrode deliver a positive current/charge of at least 50 μA , since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art.

22. As to Claim 36, Michelson discloses the claimed invention as discussed above except that the current effective to inhibit/reduce bone growth is not specified to be at least 35 μA . It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the power source and the at least one electrode deliver a positive current/charge of at least

Art Unit: 3766

35 μ A, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art.

Response to Arguments

23. Applicant's arguments filed November 9, 2005 in regards to Claims 1, 3-7 and 18 have been fully considered but they are not persuasive. The Examiner takes the position that "to reduce" is encompassed by the definition of "to inhibit". Moreover, Applicant's Title uses the terminology "current induced *inhibition* of bone growth" and to argue that inhibiting bone growth does not reduce bone growth is false. Also, Applicant states that a current high enough to inhibit bone growth will also "reduce or stop growth of treated bone" on page 10, paragraph 37 of the disclosure. In addition, the "positive electrical charge" applied to the desired location of the bone where growth is not desired or where bone growth is to be inhibited by device 10 of Michelson is supplied by the power source 60 of control circuitry 70 comprising means for providing "various patterns of direct current, alternating current, pulsatile current, sinusoidal current etc." (see Michelson column 9, lines 30-45). "Positive current" and "positive charge" applied to the bone are one in the same and are used interchangeable throughout the disclosure of the device 10 of Michelson (see Michelson column 8, lines 41-43).

24. Applicant's arguments with respect to claims 2, 8-9, 20-24 and 29 have been considered but are moot in view of the new ground(s) of rejection.

25. Applicant's arguments, see Applicant's Remarks pages 19-20, filed November 9, 2005, with respect to Claims 10-14, 17 and 25 have been fully considered and are persuasive. The rejection of August 9, 2005 has been withdrawn.

Allowable Subject Matter

26. Claims 10-17 allowed.
27. Claims 19, 25 and 32-35 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
28. The following is an examiner's statement of reasons for allowance: The references of the prior art fail to show or teach a method of reducing/inhibiting the growth of a bone comprising applying bone growth reducing current to at least a portion of the growth plate. The references of the prior art also fail to show a method where the amount of correction for the curvature of the spine is determined, the change in curvature of the spine is monitored and electrode used to apply current to the spine is removed from the vertebra when the amount of correction for the curvature of the spine has been achieved. The references of the prior art further fail to provide a method as disclosed by Michelson and discussed above where a electrode is positioned in a first vertebra and an electrode is positioned in a second vertebra and applying more current to the vertebra at the apex of the curve of the spine than to the first and second vertebra to effect the curvature of the spine.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

29. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

30. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica L. Reidel whose telephone number is (571) 272-2129. The examiner can normally be reached on Mon-Thurs 7-4:30 and every other Friday 7-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jessica L. Reidel
Examiner
Art Unit 3766

01/04/06



Robert E. Pezzuto
Supervisory Patent Examiner
Art Unit 3766